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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,695	06/11/2001	Gregor Reid	12139Z	3974

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,695

Applicant(s)

REID ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 5, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6, 11, 13, 18, 20, 26 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 7, 10, 12, 14, 17, 19, 21, 22, 25, 27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

This application filed June 11, 2001, is a continuation in part of 09/459,292, filed December 10, 1999, now US Patent 6,479,051.

Claims 1-29 are pending.

Election/Restriction

Applicant's election with traverse of Group I, claims 3, 5, 7, 10, 12, 14, 17, 19, 21, 25, 27 and 29 in the reply filed on April 5, 2004 is acknowledged. The traversal is on the ground(s) that the restricted inventions are interrelated and interdependent not independent and distinct.

Applicants argue that it is in the public interest and the courts have maintained that several aspects of an invention can be claimed together independent of the number of statutory classes. Further, the use of classification has no statutory basis as evidence of independence and distinctness. See Applicants' response, pages 3-5. This is not found persuasive because for a proper restriction one of two standards must be met: 1) the inventions must be independent or distinct, and 2) there must be a serious burden on the examiner if restriction is not required of a proper restriction has been met (MPEP 806.04 and 808.02). In this case, Applicants arguments that the inventions are interrelated does not establish that the inventions are not distinct. A search of *Lactobacillus* would not identify *Bifidobacterium*, or even more generally as encompassed by the linking claims, a search for a probiotic would not necessarily identify either *Bifidobacterium* or *Lactobacillus*. *Bifidobacterium* and *Lactobacillus* may be related as probiotics, however they represent distinct products. Further, their individual use in any given

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method would require specific search and consideration of each in the context of the claimed method.

Examiner would agree, as set forth in the restriction requirement, that the product of group III can be used in the method of group I, however it is noted that it would not be used in the method of group II. Further, it is noted that if the product was elected, method claims making or using the product commensurate in scope with the product would be rejoined. In this case, because the product set forth in claim 22 is recited in the elected method claims and will be searched in this context, Groups I and III are rejoined because there should not be a search burden. However, the restriction of group II is maintained because it does not use the product of group III, and represents use of a distinct product as argued above. Finally, it is noted that MPEP 808.02 states that 'the Examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation of one of the following: (A) Separate classification, (B) Separate status in the art when classifiable together, or (C) a different field of search'. In this case, Examiner has demonstrated both B and C for restricting Group II from rejoined groups I and III.

With respect to group II, it is noted that because it has been claimed in a linking claim, upon the **allowance** of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-29 are pending. Claims 4, 6, 11, 13, 18, 20, 26 and 28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 5, 2004. Claims 3, 5, 7, 10, 12, 14, 17, 19, 21, 22, 25, 27 and 29, drawn to a method of improving vaginal health comprising delivering a probiotic organism wherein said organism is a *Lactobacillus*, and the product consisting of *L. rhamnosus* GR-1 and *L. fermentum* RC-14 are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Applicant has complied the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120. The instant application has been indicated to be a continuation in part of 09/459,292 and review of the specifications indicates that they are not identical. Applicants have not pointed out what new material has been added that requires the instant application to be a continuation in part, however a review of the pending claims in light of the teachings of 09/459,292 indicates that the claims under examination are fully supported. Therefore, the pending claims are given the priority date of December 10, 1999, the effective filing date of 09/459,292.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 14, 21, 22 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention recites two specific *Lactobacillus* strains *L. fermentum* RC-14 and *L. rhamnosus* GR-1 for use in the claimed methods and as individual products. Since the bacterial strains are essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the strains are not so obtainable or available, the requirements of 35 U.S.C. 112, regarding “how to make”, may be satisfied by a deposit of cell lines. It is noted that *L. rhamnosus* GR-1 has an ATCC deposit number (specification page 9, line 12), but there is no indication in the specification as to public availability. With respect to *L. fermentum* RC-14 there is no ATCC deposit number (specification page 9, line 31. If the deposit of *L. rhamnosus* GR-1 was made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific cell lines have been deposited under the Budapest Treaty and that the cell lines will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit

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requirement for *L. rhamnosus* GR-1. For *L. fermentum* RC-14, evidence of a deposit or deposition of the recited strain must be made.

It the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request of for the effective life of the patent, whichever is longer; and,
- (d) a test of viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Linking claim 1 is rejected under 35 USC 102(b) as being anticipated by Ford *et al.* (5,635,202) or Velraeds *et al.* (App Env Microbiol 62(6):1958-1963, June 1996).

Both Ford *et al.* and Velraeds *et al.* teach application of lactobacillus for the colonization of the urogenital tract to prevent and treat colonization of uropathogenic flora.

Claims 1, 3, 5, 7, 10, 12, 14, 17, 19, 21, 22, 25, 27 and 29 are rejected under 35 USC 102(b) as being anticipated by Reid *et al.* (5,645,830).

Reid *et al.* teach to use *L. rhamnosus* GR-1 (see for example claim 8) for the treatment and prevention of a variety of urogenital microbial infections. It appears that *L. fermentum* RC-14 is also termed or is a variation of *L. acidophilus* RC-14 (as evidenced by Velraedes *et al.* in light of Heinemann *et al.* FEMS Micro. Let. 190:177-180, 2000 page 177, ref. [7])

Therefore, Reid *et al.* teach species recited in the claims and thus, anticipate the claims.

Claims 1, 3, 5, 7, 10, 12, 14, 17, 19, 21, 22, 25, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Reid *et al.* (Clin. Micro. Rev. 335-344, 1990).

Reid *et al.* teach to use *Lactobacillus* for the treatment and prevention of a variety of urogenital microbial infections including vaginitis (page 340). More specifically, Reid *et al.* teach to use *L. casei* GR-1 (page 339) which also appears to be termed *L. rhamnosus* GR-1 for the treatment and prevention of a variety of urogenital microbial infections.

Therefore, Reid *et al.* teach a species recited in the claims and thus, anticipate the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5, 7, 10, 12, 14, 17, 19, 21, 22, 25, 27 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,479,051. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods that establish a healthy urogenital flora is the same conditions that improve vaginal health as instantly claimed. It is noted that the instant application is a continuation in part of '051, however the guidance for administration and types of probiotics taught in each specification are the same. In addition, the claims of '051 recite the administration of "at least one" (claim 1) allowing for the administration of more than one anticipating the instant invention that recites the administration of a second probiotic organism and is obvious in light of the teachings of the specification.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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US Patent 6,613,549 discloses the use of *L. rhamnosus* GR-1 and *L. fermentum* RC-14 for the treatment and/or prevention of gastrointestinal infection. While the method steps for administration are the same between the two specifications and consequently practicing one method would result in accomplishing the intention of the other, '549 provides no disclosure for treatment of urogenital infection as instantly claimed.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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